

PATENT
Application No. 10/776,882
Docket No. 59004.US

REMARKS/ARGUMENTS

Claims 1-18 are pending. Claims 1 and 4-14 are amended. Claims 15-21 are new.

Applicants note with appreciation the Examiner's indication that the claims, as recited, are free of prior art.

The claims stand rejected as follows:

Claims	Rejection
1-14	35 U.S.C. 112, first paragraph
1-14	35 U.S.C. 112, second paragraph

The rejections under Section 112, second paragraph, are believed to be obviated by the foregoing amendments.

The rejections based on Section 112, first paragraph, are respectfully traversed.

The Examiner's position is stated on pages 2-4 of the Office Action.

The initial burden of establishing a prima facie case of unpatentability based on non-enablement under Section 112, para. 1, rests on the Examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

To be enabling, the Specification must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). As long as "undue experimentation" is not involved, a Specification will comply with the enablement requirement of the statute even if a reasonable amount of experimentation is necessary to practice the claimed invention. Enzo Biochem Inc. v. Calgene, 188 F.2d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir. 1999). That is, even a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. See, In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1401, 1404 (Fed. Cir. 1988).

The factors considered in determining whether undue experimentation is required to practice a claimed invention, include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art;

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(6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims. Consideration of every one of these factors is not mandatory. Rather, consideration is generally given only to those factors relevant to the facts of the case. See, Amagen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991).

The Examiner asserts (page 3) of the Office Action:

The amount of direction or guidance present: - the instant specification fails to provide guidance on how just the charged colloidal particles, when electrostatic interact with the solid support with just molecular structures on it, can detect the pattern of molecular structures.

In the present case, the Specification gives explicit guidance with respect to detection of patterns of molecular structures. For example, at page 13, lines 11-28 of the Specification, the following description is provided:

9. During the binding and post binding treatment disclosed herein above a latent pattern of molecular structures is formed on the substrate surface. This pattern now can be visualized by exposing, i.e., developing the substrate in a solution of colloidal particles. During the development step particles are bound to the substrate thereby producing a thin layer of colloidal material on the surface. The density of colloidal material varies from site to site following the pattern of molecular structures on the surface. Therefore, by measuring the density of colloidal material on the surface it is possible to identify the location and also it is possible to measure the quantity of probe-target complexes on corresponding sites of the surface. The concentration of colloidal particles in solution and the temperature influences the rate of development of the image. While solutions that are used may be at a starting temperature of about 0°C or even below, the development temperature is generally maintained in the range of about 1°C to about 90°C. The results from 4°C to 50°C depending on the nature of the sample, appears preferable. Temperatures below 20 °C can also be used to prevent denaturation of probe-target complexes providing latent pattern development is controlled. The temperature, if not controlled during the development, may rise above the preferred ranges. Temperature requirements may be varied by one skilled in the art depending on the nature, characteristics, and the chemical components of the developing solution.

The Examiner also asserts (pages 3-4) of the Office Action:

The presence or absence of working examples: - there is no examples in the specification that show detection of the pattern of molecular structures on the solid support is possible by contacting the solid support with just a colloidal particles which interacts with the solid support by electrostatic interaction.

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Applicant respectfully disagrees with the Examiner's conclusion in regard to an absence of working examples. For example, working prototypes, guidance and protocols for detecting molecular structures on a solid support are presented and discussed in connection with Figure 2, (detection of polypeptide Poly-L-lysine) Figure 4 (detection of M13 phage DNA), Figure 5 (detection of protein IgG and protein A) and Figure 6 (detection of hybridized oligonucleotides). Example of protocols which include type of reagents used, working concentration, order of applying the reagents, and time of treatment are described in accompanying figure captions (see [0034], [0035]) and also are disclosed in Examples I-VI ([0053]-[0071]) of the Specification.

Given this guidance, it is submitted that the Examiner has not adequately established that any experimentation would be "undue." Accordingly, withdrawal of the rejection under 35 U.S.C. Section 112, para. 1, is respectfully requested.

Applicant does not intend to surrender any range of equivalents under the Doctrine of Equivalents in regard to any claim limitation that appears in the final claims in any patent that may issue from this or any related application. Applicant expressly reserves the right to resort to the Doctrine of Equivalents for all limitations in regard to any future assertion of infringement of any claim, whether the limitation was present in an original claim or added by amendment a claim to or referenced in any argument to distinguish any claim from any prior art. All claims in any patent issued from this or any related application represent a statutorily presumed valid and patentable combination of structure and/or steps, and it is this combination which is presumed to patentably distinguish from the prior art, not any particular limitation of any claim.

Reconsideration and issuance of a notice of allowance is requested. In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355**.

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